

**REMARKS**

Applicants have received and reviewed the Office Action dated May 31, 2011. By way of response, Applicants present the remarks below. Applicants have amended claims 1-7. No new matter has been added. Claims 1-7 are pending. Applicants submit that the amended claims are supported by the specification as filed.

For the reasons presented below, Applicants respectfully submit that the amended claims are in condition for allowance, and notification to that effect is earnestly solicited.

**Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph**

The Examiner rejected claims 1, 5, 6 and 7 under 35 U.S.C. § 112, second paragraph. The Examiner objected to claim 1 for referring to a table and to claim 7 for reciting “improved”. Applicants respectfully traverse this rejection.

Claim 1 no longer refers to a table and claim 7 no longer recites “improved”, which obviates this rejection. The claims were amended solely to expedite prosecution of the present claims and not to acquiesce to the rejection.

Accordingly, Applicants respectfully submit that the amended claims fully comply with § 112, second paragraph, and withdrawal of this rejection is earnestly solicited.

**Rejections of Claims Under 35 U.S.C. §§ 102(b) and 103(a)**

The Examiner rejected claims 1-7 under 35 U.S.C. § 102(b) as anticipated by Zimmermann et al., WO 99/03854. The Examiner rejected claims 1-7 were rejected under 35 U.S.C. § 103(a) as obvious over Zimmerman et al. Applicants respectfully traverse these rejections.

The Office Action asserts that the Zimmerman et al. reference discloses a form of Imatinib mesylate with differences from the claimed invention that are “negligible”. Applicants respectfully disagree. In addition, Applicants respectfully submit that the present patent application as filed includes the information required to establish the significant differences between Applicants’  $\alpha_2$ -form crystal from the  $\alpha$ - and  $\beta$ - forms disclosed in the Zimmerman et al. reference.

First, the powder XRD spectrum of Applicant's  $\alpha_2$ -form has a peak at an angle of diffraction ( $2\theta$ ) of 18.6 degrees having a high intensity of 95-100%. This intense peak is lacking in spectrum of the  $\alpha$ -form disclosed in the Zimmerman et al. reference. This intense peak is listed in the table in claim 1 as having an intensity of 98.8, and this Table also appears in the text of the application as Table I. Figure 1 of the present application illustrates this intense peak. It is clear that the spectrum of the  $\alpha$ -form reported in the Zimmerman et al. reference does not have this intense peak (Figure 1 of the Zimmerman et al. reference).

Second, the presently claimed  $\alpha_2$ -form has a different crystal shape than the  $\alpha$ -form reported in the Zimmerman et al. reference. The  $\alpha$ -form reported in the Zimmerman et al. reference forms needle shaped crystals (page 2 and Figure 3 of the Zimmerman et al. reference) that are not free flowing. As reported at Table 7, page 15, of the present application, crystals of Applicants'  $\alpha_2$ -form are not needle shaped and are free flowing. The present independent claims recite that the present crystals are not needle shaped and are free flowing. Accompanying Exhibit A shows photographs illustrating the different shapes of the crystals.

Third, differential scanning calorimetry (DSC) indicates a melting point of 222-223 °C for Applicants'  $\alpha_2$ -form. A determination of this melting point is illustrated in Figure 3 of the present patent application, which indicates 223.6 °C. In contrast, the Zimmerman et al. reference reports the melting point of the  $\alpha$ -form as 226 °C (at page 5). These values are distinct.

Fourth, as reported in Table 7 in the present application, Applicants' claimed  $\alpha_2$ -form is not hygroscopic. As reported at page 2 of the Zimmerman et al. reference, the  $\alpha$ -form is hygroscopic. This is another difference, reported in the present specification, between the presently claimed  $\alpha_2$ -form and the  $\alpha$ -form disclosed in the Zimmerman et al. reference.

In addition, unexpected properties of the presently claimed  $\alpha_2$ -form with respect to the  $\beta$ -form disclosed by the Zimmerman et al. reference include an advantageously more rapid dissolution profile. Table 6 (at page 14) of the present application compares dissolution of the claimed  $\alpha_2$ -form and the  $\beta$ -form disclosed in the Zimmerman et al. reference. After 5 minutes, about twice as much of the  $\alpha_2$ -form has dissolved compared to the  $\beta$ -form. At 15 minutes, more than 90% of the  $\alpha_2$ -form has dissolved, but less than 70% of the  $\beta$ -form has dissolved. Faster dissolution of the  $\alpha_2$ -form presents a real world advantage in therapy. The Zimmerman et al.

reference does not disclose or suggest arriving at faster dissolving forms of Imatinib or any advantage of a faster dissolving form.

Accordingly, the present application as filed provides proof that the presently claimed  $\alpha_2$ -form is novel and non-obvious with respect to the Zimmerman et al. reference. Applicants respectfully request withdrawal of these rejections.

**Summary**

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

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MTS:kf

  
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